K103220

APPENDIX 12 – 510(K) SUMMARY

Voyager Peritoneal Dialysis (PD) System

JUL 29 2011

Applicant

DEKA Research & Development Corporation
340 Commercial Street
Manchester, NH 03101-1129

Contact Information

Name:	Roger Leroux, Director of Regulatory and Clinical Affairs
Telephone:	(603) 669-5139
E-mail:	rleroux@dekaresearch.com
Date Prepared:	October 29, 2010

Device

Proprietary Name:	Voyager Peritoneal Dialysis (PD) System
Common/Usual Name:	Automated Peritoneal Dialysis (ADP) Cycler
Classification:	Peritoneal dialysis system and accessories per 21 CFR 876.5630
Device Class	II
Product Code:	FKX

Predicate Devices

The Voyager Peritoneal Dialysis (PD) System is substantially equivalent to the HomeChoice Automated Personal Cycler, which was previously cleared under applications K053512, K012988, and originally K923065. The Voyager System has the same intended use (with the exception that it is not intended for pediatric use) and similar technological characteristics.

The Voyager device is also substantially equivalent to the Fresenius Liberty Cycler and Disposable Cycler Set which was cleared under application K043363.

Device Description

The Voyager Peritoneal Dialysis (PD) System is used for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis therapy. The Voyager Peritoneal Dialysis (PD) System automatically cycles peritoneal dialysis fluid in the amounts and time prescribed by a clinician.

Indications for Use

The Voyager Peritoneal Dialysis System is intended for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis

All therapies using the Voyager Peritoneal Dialysis System must be prescribed and performed under the responsibility of a physician who is familiar and well informed about peritoneal dialysis.

Assessment of Non-clinical Data

The Voyager Peritoneal Dialysis System has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates. Device hardware is certified to applicable safety standards

Full system validation and software regression testing was performed to ensure that the device functions as intended. Testing included:

- Software validation and regression testing.
- Electromagnetic compatibility (EMC) testing
- Electrical safety testing
- Human Factors Testing

The results from the testing demonstrated that all modifications functioned as intended and met pre-determined acceptance criteria.

Electromagnetic compatibility testing (EMC) was conducted according to the IEC 60601-1-2. The device was found to meet the requirements defined in that document.

Electrical safety testing was conducted according to IEC 60601-1. The device was found to meet the requirements put forth in that document.

Assessment of Clinical Data

Not applicable

Conclusion

Validation and Verification testing was successful in demonstrating that all design requirements have been met. Bench testing, simulated use testing, and human factors

testing were performed on the Voyager Peritoneal Dialysis System to support substantial equivalence to the predicate device and demonstrate that the device performs as intended and is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Roger A. Leroux
Director of Regulatory and Clinical Affairs
DEKA Research & Development Corporation
340 Commercial Street
MANCHESTER NH 03101

JUL 29 2011

Re: K103220
Trade/Device Name: Voyager Peritoneal Dialysis (PD) System
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: July 19, 2011
Received: July 20, 2011

Dear Mr. Leroux:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K103220

Device Name: Voyager Peritoneal Dialysis (PD) System

Indications for Use:

The Voyager Peritoneal Dialysis System is intended for automatic control of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis.

All therapies using the Voyager Peritoneal Dialysis System must be prescribed and performed under the responsibility of a physician who is familiar and well informed about peritoneal dialysis.

Prescription Use ___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103220